In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 07-438V
April 28, 2008
To be Published

MILLMAN, Special Master

DECISION¹

Petitioner filed a petition on June 28, 2007, under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., alleging that she developed Guillain-Barré Syndrome (GBS) as a consequence of receiving influenza virus vaccine on March 25, 2002.

¹ Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

According to her petition, petitioner was born on July 15, 1948 and received her vaccination at Eckerd Pharmacy in McKinney, Texas. Petition, ¶¶ 1, 3. She states that she began feeling ill on the morning of March 28, 2002, which was three days after vaccination. She states that, three hours later, she awoke but was unable to get out of bed. She tried to stand but could not. ¶ 4. She was taken to the emergency room (ER) of the Osteopathic Medical Center of Texas at Fort Worth where she was diagnosed with GBS. *Id*.

Petitioner filed an affidavit dated June 25, 2007 which tracks the allegations of her petition. P. Ex. 1. She states that, on March 28, 2002, her husband made breakfast, but as she ate, she became nauseated. She went back to bed and fell asleep. When she awoke, she could not move her legs and has never walked again. Her husband and their landlord Mark had to carry her to the car and her husband drove her to the Osteopathic Medical Center of Texas in Fort Worth, Texas. She went into a coma. *Id*.

Petitioner's husband filed an affidavit dated June 25, 2007. P. Ex. 2. His affidavit is similar to petitioner's.

Because there is no proof of vaccination, the undersigned ordered petitioner on February 13, 2008 to file a memorandum of recitations in the medical records in which petitioner stated she received flu vaccine before she had GBS.

On March 12, 2008, petitioner filed two pages from her extensive medical records, one dated two years after the alleged vaccination, dated January 15, 2004 (Ex. 13, p. 18), and the other dated three years after the alleged vaccination, dated March 22, 2005 (Ex. 8, p. 1).

On April 2, 2008, respondent filed a Motion to Dismiss stressing the lack of any contemporaneous history of petitioner's receiving a flu vaccination on March 25, 2002.

Petitioner has the burden of proving by a preponderance of the evidence all the elements of a petition, including that she received a vaccination. 42 U.S.C. §§ 300aa-11(c)(1)(A) and -13(a)(1)(A). Althen v. Secretary of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

On April 3, 2008, petitioner filed her Response to Respondent's Motion to Dismiss. Petitioner states that her counsel "made very considerable efforts" to obtain the requisite documentation without success. She concludes:

In response to respondent's motion to dismiss, petitioner stands mute and further requests that the special master rule on the record as filed with the court.

Response, p. 2.

The undersigned had her law clerk contact petitioner's counsel to determine if petitioner and her husband wanted to give testimony on the issue of vaccination. In a voice message and an e-mail dated April 24, 2008 from petitioner's counsel to the undersigned's law clerk, petitioner's counsel states that petitioner and her husband cannot add anything more to what they already stated in their affidavits and what petitioner stated in her petition. Petitioner "has no receipt or other proof of having received the vaccination and all our extensive efforts to locate pharmacy records have been fruitless. There is really nothing more for our clients to add in order to elaborate on those facts."

FACTS

Before the Alleged Vaccination

On October 7, 1993, petitioner had a brain MRI done. P. Ex. 12, p. 65. Petitioner complained of memory loss and had multiple trauma. She had abnormal areas of increased

signal in the white matter bilaterally high over the convexities, more prominent on the right of midline. Dr. Frank E. Brown was highly suspicious of multiple sclerosis. *Id.*

On April 14, 1998, petitioner had another brain MRI done. *Id.* at 66. She complained of migraines and vertigo. There were fairly extensive white matter changes involving the right frontal lobes, extending into the parietal regions. FLAIR images demonstrated a focus of abnormal white matter signal measuring roughly 8 mm in the genu of the corpus callosum, highly suggestive of demyelinating disease. There was a small focal area adjacent to the right lateral ventricle that suggested demyelinating disease as well. *Id*.

On June 4, 1998, petitioner saw Dr. Ganana Tesfa, a neurologist. *Id.* at 59. She had a diagnosis of probable multiple sclerosis (MS). Five years previously, she lost her bladder control followed by intermittent short memory loss, right leg weakness, and photophobia. She had almost constant bilateral upper extremity paresthesia for two months, left greater than right. She had intermittent proximal left upper extremity pain and right hand weakness for four to six weeks. She had neck pain for one month. She woke at night due to upper extremity pain, which worsened when driving. She had a history of daily headache for three weeks. This was associated with nausea, photophobia, and phonophobia lasting up to a day. She had had severe headache for 30 years. She had a history of diabetes, hypertension, and depression. She had a 20-year history of smoking. *Id.*

After the Alleged Vaccination

Petitioner alleges she received an influenza vaccination on March 25, 2002.

On March 30, 2002, petitioner went to the Emergency Department of the Osteopathic Medical Center of Texas. P. Ex. 15, p. 10. She reported that, on March 29, 2002, she began

having difficulty ambulating. Her right leg was affected and she was incontinent of urine. She was wearing a diaper and her mucous membranes were dry. She was able to tolerate oral fluids. *Id.* at 16. [Petitioner alleges in her petition that the onset was March 28, 2002. Her prior medical records show difficulty with bladder control.]

On March 30, 2002, petitioner was admitted to the Osteopathic Medical Center of Texas, and discharged on May 8, 2002. *Id.* at 23. She was under the care of Dr. Phillip E. Cohen. The Discharge Summary notes that petitioner entered the ER with right upper extremity and right foot weakness, and slurred speech that started that morning. She stated she had a history of prior cerebrovascular accident, heart disease, hypertension, and non-insulin dependent diabetes mellitus. *Id.* She was admitted to the hospital with a diagnosis of acute cerebrovascular accident. *Id.*

On March 30, 2002, Dr. Cohen wrote an extensive history and did a physical. *Id.* at 25. Petitioner stated that she had right upper extremity weakness, right foot weakness, and slurred speech since 9:00 a.m. that day. She also had nausea, generalized headache, and dysphagia. In October 2000, she had a prior cerebrovascular accident with residual left upper extremity weakness. Her prior medical history included heart disease, hypertension, hepatitis A 30 years previously, multiple sclerosis, recurrent urinary tract infections, hypertension, cerebrovascular accident, non-insulin dependent diabetes mellitus, pneumonia, and cervical cancer. *Id.* She had a tonsillectomy, appendectomy, and cervical conization 12 years previously. She smoked one pack of tobacco per week but did not drink or take drugs. *Id.* She had three children. Her mother died at 72 years of age from heart disease and had a history of hypertension and non-insulin dependent diabetes mellitus. Her father died at 44 years of age of coronary artery disease

and had a history of hypertension. Petitioner was hospitalized in 1995 for heart trouble. She had numerous hospitalizations at John Peter Smith secondary to trauma from physical abuse by her ex-husband. She had a history of head trauma and multiple concussions, but denied any long bone or cranial bone fractures. Id. She denied any change in appetite, sleep or elimination, or positive intense weight loss. She denied vertigo, syncope, or significant cephalgia or migraine. She denied any color blindness, diplopia, cataracts, or glaucoma. She had a history of sinusitis and seasonal allergies. She denied tenderness or lesions to oral cavities, or persistent hoarseness or dysphagia. She did not have a history of goiter, but did have thyroid problems 35 years previously. She had a history of tinnitus in the right ear, but no history of pain, deafness, or mastoiditis. Id. She had a history of hypertension, heart disease, orthopnea, and dyspnea on exertion but no history of claudication. Id. She had a history of pneumonia and cough secondary to postnasal drainage, but no history of wheezing, hemoptysis, pleurisy, asthma, or tuberculosis exposure. Id. at 26. She did not have hepatitis A, gastroesophageal reflux disease, recurrent nausea, vomiting, hematemesis, diarrhea, or constipation, melena, or hematochezia. She had recurrent urinary tract infections. She gave a history of multiple sclerosis. She was positive for prior cerebrovascular accident. Id.

On physical examination, petitioner was in no acute distress, was alert and oriented times three. She had normal affect. Her deep tendon reflexes were 2+ bilaterally for the upper extremities, and 1+ bilaterally for the lower extremities which Dr. Cohen thought was likely secondary to diabetic neuropathy. *Id.* Dr. Cohen diagnosed petitioner with stroke, transient ischemic attack, and status post prior cerebrovascular accident and residual left upper extremity weakness, with a history of hypertension, non-insulin dependent diabetes mellitus, and multiple

sclerosis. *Id.* at 26-27. [Neither petitioner nor her husband gave a history of her having received flu vaccine.]

On April 15, 2002, while still hospitalized at Osteopathic Medical Center of Texas, petitioner saw Dr. Michael Carnes because of neck spasms with mild neck discomfort. *Id.* at 28. Petitioner's family gave a history that petitioner complained of a flu-like syndrome that occurred approximately one week prior to her admission. *Id.* [They did not say she had received a flu vaccination.]

During her stay in the hospital, petitioner began to complain of extremity weakness, noted on April 8, 2002. The diagnosis was probable GBS. It was felt that her subjective flu-like illness prior to her admission triggered her GBS. *Id.* Petitioner denied any changes in her bowel habits, but the chart notes that she had several episodes of constipation during her hospitalization, most notably on April 1, 2002. *Id.* at 30. On questioning about her history of multiple sclerosis, petitioner said it was a misdiagnosis and did not know where the diagnosis came from. *Id.*

On physical examination, petitioner was alert and oriented times three and in no acute distress. *Id.* at 31. She had a very flat affect with slowed responses to questioning. *Id.* She diverted her gaze away from the examiners secondary to her husband making somewhat chastising remarks about her. She also had multiple crying episodes and apologized profusely because she felt she had offended the examiners. *Id.* The diagnosis was GBS, depression, hypertension, diabetes, MS by history, obesity, coronary artery disease, and degenerative joint disease of the lumbosacral spine per MRI. *Id.* at 32-33.

On June 10, 2002, petitioner returned to the Osteopathic Medical Center of Texas after discharge on May 15, 2002, giving a history of lethargy and hypotension that morning, making it

difficult for her to wake up. *Id.* at 1202. [Petitioner did not give a history of her having received flu vaccine before her GBS.]

On June 12, 2002, petitioner had a neurological examination. *Id.* at 1263-64. The doctor notes that petitioner had multifocal lesions (neuropathy/cerebrovascular accident) which suggested possible vasculitis. The lab results did not show an obvious etiology. A nerve biopsy was positive for GBS, but equivocal for an inflammatory course. *Id.* at 1264.

Petitioner was discharged on June 24, 2002 with a diagnosis of GBS, urinary tract infection, diabetes mellitus, and obesity. *Id.* at 1206. She was transferred on June 24, 2002 to the HealthSouth Rehabilitation Hospital of Fort Worth. P. Ex. 9, p. 4.

On June 24, 2002, petitioner gave her history to Dr. S.K. Nair. *Id.* at 5. Dr. Nair diagnosed a moderately severe peripheral neuropathy which might be secondary to GBS and/or diabetes mellitus. *Id.* at 6. She was discharged on July 22, 2002. *Id.* at 4. [Petitioner never mentioned receiving flu vaccine before her GBS.]

On August 2, 2002, petitioner saw a psychologist due to depression. *Id.* at 339. Petitioner reported multiple recent stressors. She was diagnosed with GBS in March 2002 after she experienced paralysis overnight. She said she had been in and out of coma. He husband had undergone quadruple bypass surgery. Her best friend and her husband were murdered by the couples' daughter, and she described her life visiting nursing homes. *Id.* Petitioner had been married for five years with three children. Her husband had 11 children from four previous marriages. Her medical history included heart disease, hypertension, cerebrovascular accident, non-insulin dependent diabetes, pneumonia, tonsillectomy, appendectomy, and cervical conization 12 years ago. Petitioner was alert and cooperative, oriented times three. Her speech

was good and oriented. There were no delusions or hallucinations. Her sleep and appetite were poor as was her energy. Her motivation was good. The psychologist diagnosed her with major depressive disorder. *Id.* [Petitioner never mentioned that she received flu vaccine before her onset of GBS.]

From August 24, 2002 to September 25, 2002, petitioner was in HealthSouth

Rehabilitation Hospital of Arlington. P. Ex. 10, p. 13. Petitioner gave a history of having

multiple cerebrovascular accidents with resultant spastic left hemiparesis and GBS. *Id.*Petitioner gave a pre-admission history on August 23, 2002, telling nurse Janice L. Johnson that
she had previously enjoyed a very active lifestyle. She volunteered in the neighborhood, was a
community ambulance helper and driver, and was independent in all areas. In March 2002, she
suffered multiple cerebrovascular accidents and was subsequently diagnosed with GBS. She had
a stay at Osteopathic under the care of Dr. Philip Cohen. She was transferred to HealthSouth

Downtown Ft. Worth on June 24, 2002 and discharged July 22, 2002 to Manor Care. Petitioner
told of a difficult stay at Ft. Worth. She had significant depression secondary to tremendous
decrease in function and also suffered the loss of a very close friend. She was currently receiving
psychologic therapy to help her through the grieving process. She was pleasant, cooperative, and
motivated to return to an independent functional level. *Id.* at 327. [Petitioner never said she
received flu vaccine before her onset of GBS.]

On March 17, 2003, petitioner gave a history at the University of South Alabama

Hospitals of a sudden onset of lower extremity weakness associated with sudden onset of flu-like symptoms and myalgias in March 2002. P. Ex. 13, p. 36. On March 19, 2003, an initial data base notes that petitioner had GBS with sudden onset of lower extremity weakness and flu-like

symptoms. P. Ex. 13, p. 104. [Petitioner did not give a history of her having received flu vaccine before her onset of GBS.]

However, on March 18, 2003, according to Humana Military Healthcare Services Medical Services Review, petitioner's husband made a statement that petitioner received a flu shot in March 2002, became ill with fever and flu-like symptoms and subsequently was diagnosed with GBS. P. Ex. 3, p. 2. She also suffered a cerebrovascular accident at or around the same time. *Id.* According to a history given at outpatient therapy in December 2002, petitioner had had three strokes with residua, the last stroke occurring in March 2002. *Id.* This is the first notation in the records, and comes one year after the alleged vaccination, that petitioner had received flu vaccine before her GBS.

However, neither petitioner nor petitioner's husband gave a history of flu vaccination before the onset of GBS during the University of South Alabama Hospital hospitalization from March 17, 2003 to April 10, 2003. P. Ex. 13. Petitioner's husband had been in the military and HMHS gave authorization for petitioner's treatment at the University of South Alabama Hospital in March 2003. P. Ex. 13, p. 35.

On January 20, 2004, a perioperative record for the University of South Alabama Knollwood Hospital notes that petitioner had GBS in 2002 from flu vaccine. P. Ex. 13, p. 17. This is also reflected in a preoperative assessment dated January 15, 2004. P. Ex. 13, p. 18.

On March 22, 2005, petitioner saw Dr. Ann M. Haddenhorst, an internist, and gave a history that she had adult onset diabetes mellitus for more than 10 years, GBS in 2002 after a flu shot, cerebrovascular accident and mini-strokes during her GBS, hypertension, and elevated cholesterol. P. Ex. 8, p. 1.

On April 15, 2005, petitioner saw Dr. Patricia A. Fodor and gave a history that in April 2002, she developed GBS three days after a flu shot. P. Ex. 4, p. 1. She had a stroke with loss of the use of her left arm in 2001 and loss of speech. She had had diabetes for 10 years. *Id*.

On May 2, 2005, petitioner had a brain MRI which showed encephalomalacia secondary to an old infarct. P. Ex. 4, p. 3. She also had diffuse periventricular white matter ischemic changes of the supratentorial brain. *Id*.

On June 19, 2005, petitioner went for a physical therapy initial evaluation at the Outpatient Adult Rehabilitation Services at Memorial Hospital. She told the therapist that she had a cerebrovascular accident, GBS, and left upper extremity and lower extremity spasticity. Petitioner said her past medical history was that she had sustained multiple small, minor strokes prior to her GBS diagnosis March 28, 2002. She also had a diagnosis of diabetes. She fractured her right arm in 2003. P. Ex. 11, p. 98.

On June 21, 2005, petitioner have a history at Memorial Hospital that on March 28, 2002, she was hospitalized for 22 weeks with GBS and then at HealthSouth for eight weeks. P. Ex. 11, p. 71.

On May 4, 2006, petitioner went for outpatient rehabilitation at Memorial Hospital, giving a history that she had suffered a cerebrovascular accident following GBS four and one-half years earlier. P. Ex. 11, p. 36.

By affidavit of counsel dated June 27, 2007, petitioner's counsel stated he was unable to obtain petitioner's vaccination record. P. Ex. 7. In P. Ex. 16, petitioner's counsel's paralegal further explains that after numerous attempts to obtain petitioner's vaccination record from various companies and organizations, she was unable to obtain said record.

DISCUSSION

The Vaccine Act requires, as part of the petition contents, that petitioner receive a vaccination listed in the Vaccine Injury Table. She must prove this element of her petition by a preponderance of the evidence. 42 U.S.C. § 300aa-11(c)(1)(A) and -13(a)(1)(A). Althen v. Secretary of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Not only is there no documentation of petitioner's vaccination, but also there is no proof of the date on which she allegedly received it.

On March 30, 2002, presumably five days after she received the alleged flu vaccination, she was in the hospital unable to walk. Dr. Phillip Cohen took a thorough history from her and her husband. Petitioner and her husband told Dr. Cohen of all her extensive medical history: heart disease, hypertension, hepatitis A 30 years previously, multiple sclerosis, recurrent urinary tract infections, hypertension, cerebrovascular accident, non-insulin dependent diabetes mellitus, pneumonia, cervical cancer, tonsillectomy, appendectomy, cervical conization 12 years previously, smoking one pack of tobacco per week but not taking drink or drugs, having three children, her mother dying at 72 years of age from heart disease with a history of hypertension and non-insulin dependent diabetes mellitus, her father dying at 44 years of age of coronary artery disease with a history of hypertension, her own hospitalization in 1995 for heart trouble, numerous hospitalizations at John Peter Smith secondary to trauma from physical abuse by her ex-husband, a history of head trauma and multiple concussions, but no long bone or cranial bone fractures, no change in appetite, sleep, elimination, intense weight loss, vertigo, syncope, significant cephalgia or migraine, color blindness, diplopia, cataracts, or glaucoma, having a history of sinusitis and seasonal allergies but no tenderness or lesions to oral cavities, persistent hoarseness or dysphagia, goiter, having thyroid problems 35 years previously, having a history of tinnitus in the right ear, but no history of pain, deafness, or mastoiditis, having a history of hypertension, heart disease, orthopnea, and dyspnea on exertion but no history of claudication, having a history of pneumonia and cough secondary to postnasal drainage, but no history of wheezing, hemoptysis, pleurisy, asthma, or tuberculosis exposure, and denying current hepatitis A, gastroesophageal reflux disease, recurrent nausea, vomiting, hematemesis, diarrhea, or constipation, melena, or hematochezia. In all of these detailed prior health conditions and incidents, she and her husband omitted her receiving flu vaccine three or five days earlier which was followed by the very symptoms that brought her to the hospital that day. This omission makes her having received flu vaccine highly improbable.

Moreover, petitioner saw other health personnel in 2002, both in the initial hospital and in subsequent hospitals, and never gave a history of having flu vaccine within days of her current, quite serious illness. When her family told a doctor just two weeks after her admission to the initial hospital that petitioner had had a flu-like illness one week before the onset of her symptoms, petitioner denied it. But neither petitioner nor her family said to the doctor that these flu-like symptoms followed a flu vaccination. It is not believable that petitioner could remember so many details, and her family fill in more details, of her immediate and distant medical history and yet leave out the one occurrence that was closest in time to the symptoms that brought her to the hospital.

One year later, when petitioner's husband was seeking authorization from the military for his wife to receive civilian hospital care did he state that she had GBS following a flu vaccination in 2002, but he never gave this information to the medical treaters in March 2003 and petitioner did not either.

In 2004, two years after the alleged flu vaccination, petitioner started giving a history that she had received flu vaccine followed by GBS in 2002. She repeated this history in 2005.

These histories, the earliest coming not in the context of treatment but in the context of receiving authorization for civilian medical treatment and from petitioner's husband and not petitioner, are not contemporaneous with the events at issue and are highly suspect because people's memories are less reliable as time passes. Usually the discrepancy between information in contemporary medical records and that asserted later on concerns testimony at trial. Deciders of fact prefer the earlier version which is the one in the contemporaneous medical records not only because it is earlier in time, but because the motive for the patient at the time of seeking treatment is to be as complete and truthful as possible so as to obtain an accurate diagnosis and successful treatment. United States v. United States Gypsum Co., 333 U.S. 364, 396 (1948); Burns v. Secretary, HHS, 3 F.3d 415 (Fed. Cir. 1993); Ware v. Secretary, HHS, 28 Fed. Cl. 716, 719 (1993); Estate of Arrowood v. Secretary, HHS, 28 Fed. Cl. 453 (1993); Murphy v. Secretary, HHS, 23 Cl. Ct. 726, 733 (1991), aff'd, 968 F.2d 1226 (Fed. Cir.), cert. denied sub nom. Murphy v. Sullivan, 113 S. Ct. 263 (1992); Montgomery Coca-Cola Bottling Co. v. United States, 615 F.2d 1318, 1328 (1980). Contemporaneous medical records are considered trustworthy because they contain information necessary to make diagnoses and determine appropriate treatment:

Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Cucuras v. Secretary, HHS, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

In the instant action, petitioner and her husband gave histories of petitioner receiving flu vaccine but these histories are one to three years after the contemporaneous events and differ from their numerous, extensive histories to various treaters in multiple institutions in 2002 in which they never mention a flu vaccination. Petitioner and her husband have not offered any explanation for why both of them failed to mention the flu vaccination in 2002, although given an opportunity to do so.

Petitioner has failed to make a prima facie case because she has failed to prove by a preponderance of the credible evidence that she received a flu vaccination before she had GBS.

CONCLUSION

This petition must be dismissed. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment in accordance herewith.²

IT IS SO ORDERED.

<u>April 28, 2008</u> DATE s/Laura D. Millman Laura D. Millman Special Master

² Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party's filing a notice renouncing his right to seek review.